

IMPORTANT CONSIDERATIONS FOR CLINICAL TRIAL METHODOLOGIES BERGER VANCE ZHANG XIAO%0A

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Randomized Phase II or Phase III clinical trials that are powered based on clinical endpoints, such as survival time, may be prohibitively expensive, in terms of both the time required for their completion and the number of patients required.

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In the context of randomized clinical trials, multiplicity arises in many forms. One prominent example is when a key endpoint is measured and analyzed both at baseline and after treatment.